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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,152	12/27/2000	Peter Watts	WC 110 CON	5106

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,152

Applicant(s)

WATTS, PETER

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicant's Response to Notice Missing Part filed 04/18/01, Information Disclosure Statement filed 12/27/00, Preliminary Amendment A filed 12/27/00, Amendment B filed 10/16/01, Change of Address filed 10/16/01, Amendment C filed 07/10/02, Petition filed 05/07/02, and Request for Extension of Time filed 07/10/02.

Election/Restriction

1. Newly submitted claims 14-17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original filed claims recite vaccine as the drug. Claims 14-17 additionally recite Markush group of drugs, which are distinct species from the originally claimed drug.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-17 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

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Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 6, 8-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,228,396 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the instant application are claiming common subject matter.

Claims 3, 4, and 7 are rejected under the judicially created doctrine of obviousness-type double patenting to the extent that they read on the rejected base claims.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, and 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Digenis et al. US 5,672,359.

Digenis teaches coated hard gelatine capsule made from gelatin or starch or hydrophilic polymer suitable for colonic delivery of peptide drugs (column 4, lines 20-67, column 8, lines 50-57, and examples). Example of peptide drugs are vaccines and proteins (column 8, lines 58-67).

5. Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Kelm et al. US 5,656,290.

Kelm teaches pharmaceutical dosage form for colonic delivery comprising drug encapsulated in hard capsule with coating layers, which begins to dissolve at a pH of above 5 (columns 3-4). The hard capsule can be starch or gelatin capsule, and the coating can be copolymer of methacrylic acid and methyl methacrylate, and cellulose derivatives (columns 9-11). The coating thickness is about 110 to 350 μm (columns 12-13).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelm et al., and McNeill et al. US 5,342,624.

Kelm is relied upon for the reason stated above. In the case that Kelm's priority date cannot be relied upon for the teaching of starch capsule.

McNeill teaches hard gelatin capsule or starch capsule are conventional class of capsules. It is the examiner's position that gelatin capsule and starch capsule are substantially equivalent, and therefore, it would have been prima facie obvious for one of ordinary skill in the art to modify Kelm's capsule using the starch capsule. The expected result would be pharmaceutical oral dosage form that is suitable for colonic delivery to treat colonic diseases.

7. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelm et al., and Digenis et al.

Kelm is relied upon for the reason stated above. In the case that Kelm's priority date cannot be relied upon for the teaching of starch capsule.

Digenis teaches coated hard gelatine capsule made from gelatin or starch or hydrophilic polymer suitable for colonic delivery of peptide drugs (column 4, lines 20-67, column 8, lines 50-57, and examples). Example of peptide drugs are vaccines and proteins (column 8, lines 58-67). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Kelm's capsule using the starch capsule in view of the teaching of Digenis, since Digenis teaches

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that hard gelatine capsule can be gelatin or starch or hydrophilic. The expected result would be a coated capsule useful for colonic delivery.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 an to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600